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Registration Decision RD2012-02

Metarhizium anisopliae strain F52

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Registration Decision for *Metarhizium anisopliae* strain F52

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting full registration for the sale and use of *Metarhizium anisopliae* strain F52 and the end-use product Met52 Granular Bioinsecticide, containing the technical grade active ingredient *Metarhizium anisopliae* strain F52, to control root weevils, specifically black vine weevil and strawberry root weevil, on container-grown ornamentals.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

Metarhizium anisopliae strain F52 (Registration Number 29146) and Met52 Granular Bioinsecticide (Registration Number 29147) have been conditionally registered in Canada since 2010 and the detailed review can be found in Evaluation Report ERC2010-01, *Metarhizium anisopliae* strain F52. These products were proposed for full registration in the consultation document[1] Proposed Registration Decision PRD2011-13, *Metarhizium anisopliae* strain F52. This Registration Decision[2] describes this stage of the PMRA's regulatory process for *Metarhizium anisopliae* strain F52 and summarizes the Agency's decision. The PMRA received no comments on PRD2011-13, *Metarhizium anisopliae* strain F52. This decision is consistent with the proposed registration decision stated in PRD2011-13, *Metarhizium anisopliae* strain F52.

For more details on the information presented in this Registration Decision document, please refer to PRD2011-13, *Metarhizium anisopliae* strain F52 and ERC2010-01, *Metarhizium anisopliae* strain F52 that contain detailed evaluation of the information submitted in support of this registration.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[3] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its conditions of registration. The Act also requires that products have value[4] when used according to label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

3 "Acceptable risks" as defined by subsection 2(2) of *Pest Control Products Act*.

4 "Value" as defined by subsection 2(1) of *Pest Control Products Act*"...the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact".

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (for example, children) as well as organisms in the environment (for example, those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the Pesticides and Pest Management portion of Health Canada's website at healthcanada.gc.ca/pmra.

What is *Metarhizium anisopliae* strain F52?

Metarhizium anisopliae strain F52 is a soil-dwelling fungus that causes a fatal disease in certain insects. Formulated as Met52 Granular Bioinsecticide and incorporated into the growing medium, it can provide control of root weevils, specifically black vine weevil and strawberry root weevil, on container-grown ornamentals.

Can Approved Uses of *Metarhizium anisopliae* strain F52 Affect Human Health?

***Metarhizium anisopliae* strain F52 is unlikely to affect your health when Met52 Granular Bioinsecticide is used according to the label directions.**

People could be exposed to *Metarhizium anisopliae* strain F52 when handling and applying the product. When assessing health risks, several key factors are considered: the microorganism's biological properties (for example, production of toxic by-products), reports of any adverse incidents, its potential to cause disease or toxicity as determined in toxicological studies and the level to which people may be exposed relative to exposures already encountered in nature to other isolates of this microorganism.

Toxicological studies in laboratory animals describe potential health effects from large doses in order to identify any potential pathogenicity, infectivity and toxicity concerns. When spores of *Metarhizium anisopliae* strain F52 and Met52 Granular Bioinsecticide were tested on laboratory animals, no signs of significant toxicity or disease were observed.

Residues in Water and Food

Dietary risks from food and water are not of concern.

The *Food and Drugs Act* prohibits the sale of food containing a pesticide residue that exceeds the established maximum residue limit (MRL). Pesticide MRLs are established for *Food and Drugs Act* purposes through the evaluation of scientific data under the *Pest Control Products Act*. Each MRL value determines the maximum concentration in parts per million of a pesticide allowed in or on certain foods. Food containing a pesticide residue that does not exceed the established MRL does not pose an unacceptable health risk.

As there are no direct applications to food and as no adverse effects were reported in laboratory studies, the establishment of an MRL is not required for *Metarhizium anisopliae* strain F52 under Section 4(d) of the *Food and Drugs Act* (adulteration of food) as defined under Division 15, Section B.15.002 of the Food and Drug Regulations. In addition, the likelihood of residues of *Metarhizium anisopliae* strain F52 contaminating drinking water supplies is negligible. Consequently, dietary exposure and risk are minimal to non-existent.

Occupational Risks From Handling Met52 Granular Bioinsecticide

Occupational risks are not of concern when Met52 Granular Bioinsecticide is used according to label directions, which include protective measures.

Workers using Met52 Granular Bioinsecticide can come into direct contact with *Metarhizium anisopliae* strain F52 on the skin, in the eyes, or by inhalation. For this reason, the label specifies that users exposed to Met52 Granular Bioinsecticide must wear waterproof gloves, eye goggles, a long-sleeved shirt, long pants, shoes plus socks and a dust/mist filtering respirator/mask (MSH/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator/mask with any N-95, R-95, P-95 or HE filter.

For bystanders, exposure is expected to be much less than that of handlers and mixer/loaders and is considered negligible. Therefore, health risks to bystanders are not of concern.

Environmental Considerations

What Happens When Met52 Granular Bioinsecticide Is Introduced Into the Environment?

Environmental risks are not of concern.

Metarhizium anisopliae strain F52 is a non-indigenous soil microorganism that is pathogenic to specific host insects. Since the reproduction of conidiospores is reliant upon infection of a suitable host under conditions of high humidity, the proliferation of *Metarhizium anisopliae* strain F52 in the environment would be limited. It is likely that levels of *Metarhizium anisopliae* strain F52 would return to levels comparable to native populations of *Metarhizium anisopliae*.

Toxicity testing on non-target organisms shows that *Metarhizium anisopliae* strain F52 is capable of causing some adverse effects to certain aquatic organisms when exposed to high concentrations. However, the incorporation of Met52 Granular Bioinsecticide into the growing medium of potted plants is unlikely to result in significant contamination of aquatic environments. Therefore, the risk to aquatic organisms from the use of Met52 Granular Bioinsecticide is very low. Toxicity testing also shows that terrestrial non-target organisms, other than target insect species, were not adversely affected by *Metarhizium anisopliae* strain F52 when exposed to high concentrations.

Value Considerations

What Is the Value of Met52 Granular Bioinsecticide?

Incorporated into the growing medium, Met52 Granular Bioinsecticide can provide control of black vine weevil and strawberry root weevil on container-grown ornamentals.

The value of Met52 Granular Bioinsecticide is that it provides a viable alternative for the control of certain serious pests on a variety of crops. Root weevils, particularly black vine weevil and strawberry root weevil, are major pests of many ornamentals and are considered very difficult to control. Few other pest control products are registered in Canada for use against these pests and most are older, conventional chemical insecticides. Met52 Granular Bioinsecticide must be incorporated into the growing medium to achieve acceptable efficacy, but also may remain viable for nine months after application.

Measures to Minimize Risk

Registered pesticide product labels include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures on the label of Met52 Granular Bioinsecticide to address the potential risks identified in this assessment are as follows:

Key Risk-Reduction Measures

Human Health

Due to concerns about users developing allergic reactions through repeated high exposure to *Metarhizium anisopliae* strain F52, anyone handling or applying Met52 Granular Bioinsecticide must wear waterproof gloves, eye goggles, a long-sleeved shirt, long pants, shoes plus socks and a dust/mist filtering respirator/mask (MSH/NIOSH approval number prefix TC-21C) or a NIOSH-approved respirator/mask with any N-95, R-95, P-95 or HE filter.

Environment

As a general precaution, statements have been added to the label to prohibit handlers from contaminating aquatic habitats or allowing effluent from greenhouses containing this product to enter lakes, streams, ponds or other water bodies.

Other Information

The relevant test data on which the decision is based (as referenced in PRD2011-13, *Metarhizium anisopliae* strain F52 and ERC2010-01, *Metarhizium anisopliae* strain F52) are available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa). For more information, please contact the PMRA's Pest Management Information Service by phone (1-800-267-6315) or by e-mail (pmra.infoserv@hc-sc.gc.ca).

Any person may file a notice of objection[5] regarding this registration decision within 60 days from the date of publication of this Registration Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticide and Pest Management portion of the Health Canada's website (Request a Reconsideration of Decision, www.hc-sc.gc.ca/cps-spc/pest/part/protect-proteger/publi-regist/index-eng.php#rrd) or contact the PMRA's Pest Management Information Service.

[5] As per subsection 35(1) of the *Pest Control Products Act*.